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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,179	12/01/2003	Katsutoshi Sakata	246080US0CONT	1342
22850	7590	05/22/2006	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			COLEMAN, BRENDA LIBBY	
			ART UNIT	PAPER NUMBER
			1624	
DATE MAILED: 05/22/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/724,179

Applicant(s)

SAKATA ET AL.

Examiner

Brenda L. Coleman

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 26-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/03, 2/04, 6/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-37 are pending in the application.

Election/Restrictions

1. Applicant's election with traverse of Group I in the reply filed on February 27, 2006 is acknowledged. The traversal is on the ground(s) that no adequate reasons and/or examples have been provided to support either the restriction or election requirements. This is not found persuasive because as stated by the applicants the compounds of formula XV and XVI are intermediates and the compounds of formula I are the final products. A search of the dibenzoxazepines of claims 1-25 is not inclusive of the intermediates and thus a separate search of each intermediate is independent of the other. Dibenzoxazepines of formula I differ significantly in chemical structure from the intermediate compounds of formulae XV and XVI, which are amide substituted diaryloxazepines and amide substituted 6-membered aromatic ring system, respectively, and thus are separately classified and a search for one would not yield the other.

Note MPEP 2173.05(h) "where a Markush expression is applied only to a portion of a chemical compound, the propriety of the grouping is determined by a consideration of the compound as a whole, and does not depend on there being a community of properties in the members of the Markush expression. Therefore, what should be considered for patentable distinctness is the compound as a whole. Would a whole compound where the compound is a compound of formula XV or XVI be patentably distinct from a whole compound where the compound is diaryl[b,e][1,4]oxazepine? If a

reference for one would not be a reference for the other, then restriction is considered proper. It is the compound as a whole a (R)-3-Chloro-5,11-dihydro-5-[1-(4-dimethylaminophenethyl)pyrrolidin-2-ylmethyl]dibenzo[b,e][1,4]oxazepine dihydrochloride of formula I vs. (R)-{[2-(3-Chloro-5,11-dihydrodibenzo[b,e][1,4]oxazepine-5-carbonyl)pyrrolidine]-1-yl}-2-)4-dimethylaminophenyl)ethanone of formula XV vs. (R)-1-[(4-Dimethylaminophenyl)acetyl]pyrrolidine-2-carboxylic acid [2-(2-bromo-4-chlorobenzyloxy)phenyl]amide of formula XVI, etc., that must be considered for patentable distinctness.

Thus, separate searches in the literature would be required. However, should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention..

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 26-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on February 27, 2006.

Priority

3. If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. 120, a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) must be included in the first sentence(s) of the specification following the title or in an application data sheet. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications.

If the instant application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120,

Art Unit: 1624

121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 22-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The scope of composition and method of use claims are not adequately enabled solely based on the antagonistic activity to calcium channels provided in the specification. Claims 24 and 25 are a pharmaceutical composition for use in the treatment or prevention of any and all diseases and/or disorders associated with the digestive tracts, which is not remotely enabled. The scope of claims 24 and 25 include diseases and/or disorders not even known at this time, which may be associated with calcium channel blockers. While the treatment of hypertension has been linked with calcium channel blockers, the art does not recognize use of such inhibitors as broad based drugs for treating all disorders instantly embraced. Additionally, instant claim language embraces disorders not only for treatment but also for prevention, which is not remotely enabled.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

5. Claims 1-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a) Claims 1-25 are vague and indefinite in that it is not known what is meant by "Derivative" which implies more than what is positively recited.

Art Unit: 1624

- b) Claim 1 and claims dependent thereon are vague and indefinite in that it is not known what is meant by general formula (I). A formula is not general when all of the variables are defined. Deletion of "general" is suggested.
- c) Claim 1 and claims dependent thereon are vague and indefinite in that it is not known what is meant by the variables R1, R2, R3, R4, R5, R6, R7, R8, R9, R10, R11, R12 and R13 which are not defined within the claim.
- d) Claim 1 and claims dependent thereon are vague and indefinite in that it is not known what is meant by definition of the variables R^1 to R^8 , R^9 to R^{13} , R^9 and R^{10} or R^{10} and R^{11} together where there are no such variables in the claim.
- e) Claim 1 and claims dependent thereon are vague and indefinite in that it is not known what is meant by the variable n in the moiety $-O(CH_2)_nO-$, which is not in the form of a subscript.
- f) Claim 1 and claims dependent thereon are vague and indefinite in that it is not known what is meant by the definition of Y and Z together where the moiety is $CH_2-CH_2-CH_2-CH_2$, it is believed that the applicants intended $CH_2-CH_2-CH_2-CH_2$.
- g) Claim 1 and claims dependent thereon are vague and indefinite in that it is not known what is meant by the two different definitions of the variable n.


Claim Objections

6. Claims 7-22, 24 and 25 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must be stated in the alternative. See MPEP § 608.01(n). Accordingly, the claims not been further treated on the merits.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Brenda L. Coleman
Primary Examiner Art Unit 1624
May 14, 2006